

REMARKS

Claims 1-9 and 13-56 are pending. Claims 17-32 and 35-56 have been withdrawn from consideration.

Claims 1, 3-9, 13-16, 33, and 34 have been rejected as allegedly obvious under 35 U.S.C. § 103 over U.S. Patent No. 4,831,031 to Lowe et al. ("*Lowe*") in view of secondary references (*Arenson, Lieberman*). Claim 2 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicants respectfully request reconsideration and allowance of all pending claims in view of the remarks set forth below.

I. OBVIOUSNESS REJECTION OVER *LOWE* IN VIEW OF *ARENSON* AND *LIEBERMAN*

The Examiner has rejected claims 1, 3-9, 13-16, 33, and 34 as allegedly obvious over *Lowe* in view of *Arenson* and *Lieberman*. In essence, the Examiner suggests that any amorphous form of a known compound is *prima facie* obvious, absent showing of unexpected results.

Applicants respectfully disagree.

Lowe discloses ziprasidone *per se*. *Arenson* teaches crystalline ziprasidone. *Lieberman* contains a general discussion of amorphous pharmaceutical solids. *Lowe, Arenson, or Lieberman*, alone or in combination, fail to teach or suggest the subject matter of Claim 1, taken as a whole.

To establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have a reasonable expectation of success to modify *Lowe* or *Arenson* in the direction of amorphous solids. Clearly, the existence of ziprazidone (*Lowe*) or the crystalline form of ziprazidone (*Arenson*) provides no reasonable expectation of success with regards to making an amorphous form. And while *Lieberman* may contain language about the theoretical properties of amorphous solids, it does not provide an expectation of success.

The Board of Patent Appeals and Interferences recently has rejected a conclusion of obviousness in circumstances somewhat similar to the circumstances in the present patent application. See *Ex Parte Buchi*, SI. Op., at pages 4-5. In *Buchi*, issued after the recent decision

of the United States Supreme Court in *KSR v. Teleflex*, the Examiner cited Cheronis as a secondary reference to show that use of re-crystallization is well known in the art and finding obviousness of the basis of combining Cheronis with a primary reference that taught a crystalline solid. In other words, the Examiner in *Buchi* argued that since re-crystallization is known, an artisan would employ it to arrive at the claimed polymorph. The Board rejected this reasoning, stating that while one would be expected to purify by crystallization, “that would not necessarily lead to the claimed crystalline forms.” *Id.*, at p. 5. Similarly, in the present patent application, while amorphous solids are generally known, what would provide the reasonable expectation of success?

Moreover, all teachings of the art must be considered in judging whether the art as a whole motivates an artisan to proceed in the direction of claimed invention. The Examiner refers to the following passage in *Lieberman*: “Theoretical considerations predict that amorphous solids will, in general, be better absorbed than will crystalline ones.” This passage applies to drugs in general. In contrast, *Arenson* clearly teaches the advantages of making a crystalline solid for ziprasidone specifically. See, e.g., col. 1, lines 45-50 (“it has now been determined that compositions comprising crystalline ziprasidone . . . exhibit good dissolution properties.”). Why would an artisan follow a generic teaching based on “theoretical consideration” rather than specific teaching away?

Withdrawal of all rejections over *Lowe* is respectfully requested.

II. INDEFINITENESS REJECTION

Claim 2 has been rejected as allegedly indefinite for incorporating a figure by reference. According to the Examiner, Applicants should recite the peak of the XRD pattern instead.


Applicants respectfully direct the Examiner’s attention to the nature of the XRD spectra for the amorphous material. Applicants are truly unable to claim this subject matter in different way, fully complying with the requirements of MPEP 2173.05.

Withdrawal of the indefiniteness rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-3221.

Respectfully submitted,

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